Summary of the External Review of the Office of Pesticide Program's Product Reregistration Process

March 2008

Fact Sheet

Introduction

The U.S. Environmental Protection Agency (EPA) Office of Pesticide Programs conducts a comprehensive review of pesticides initially registered before November 1, 1984, to ensure that they meet contemporary health and safety standards and labeling requirements. After the registrant signals its intent to reregister an active ingredient, EPA conducts science reviews, develops a risk assessment and publishes it for public comment, and issues a Reregistration Eligibility Decision. EPA then must reregister each of the individual pesticide products that contains the active ingredient. This final step in the process – pesticide product reregistration – is the focus of this evaluation.

The purpose of this external review of EPA's Office of Pesticide Programs product reregistration process was to identify potential opportunities for innovation and streamlining of the product reregistration process in order to (1) ensure timelier implementation of the mitigation measures required in the RED and (2) make the process more efficient.

Evaluation Questions

The evaluation was designed to answer the following questions:

1. What components of REDs have caused delays in product reregistration?
2. What problems, bottlenecks, or unnecessary duplication of efforts occur in the product reregistration process that are under the control of OPP?
3. What innovations or streamlining in process could result in more timely implementation of mitigation specified in the RED and/or more efficient production of outputs?
4. What are the pros and cons of each of the proposed innovations or streamlining measures?
5. What is the optimal allocation of tasks between the Special Review and Reregistration Division and the Registration Division?
6. Are any external entities or considerations impeding the product reregistration process?

Evaluation Methods

The methodology employed several data collection methods, including interviews with EPA staff, a review of published documents available from EPA, the Government Accountability Office, the Office of Management and Budget (OMB), industry associations, and

http://www.epa.gov/evaluate

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environmental groups served as another data source, review of reregistration program data, case studies, and consultation with subject matter experts.

Key Findings and Recommendations

Findings

- **Product Reregistration Status**

Of the approximately 20,000 pesticide products facing reregistration, 7,358 (38% have completed the reregistration process as of the end of FY'06.

4,695 products – voluntarily cancelled
2,070 products – reregistered
563 products – amended
30 products – suspended

- **Problem Quantification**

For the 2,070 products that have completed reregistration (as of the end of FY'06), the average time from RED signature to product reregistration decision was 54 months (4.5 years).

This 54 month average time is comprised of:
- 40 months – from RED signature, thru batching, DCI approval, DCI issuance, data generation, data submission, data & label reviews to package sent from SRRD to RD;
- 14 months – from receipt of package by PM in RD, thru label revisions with registrant to label approval and product reregistered.

The amount of time required to register all of the products for a RED is not a function of the number of products involved.

12,166 products associated with signed REDs are still pending reregistration (as of the end of FY'06):
- 71.4% of pending products are associated with REDs signed in 2006;
- 9.7% of pending products are associated with REDs signed in 2005;
- 13.6% of pending products are associated with REDs signed in 2000-2004;
- 5.2% of pending products associated with REDs signed prior to 2000.

- **Sources of Delay in Product Reregistration**

  - Unresolved issues in signed REDs;
  - New data submitted to rebut RED conclusions;
  - OPP's historical focus on RED completion to meet statutory deadlines;
  - Lengthy post-RED DCI justification process;
  - Lack of an integrated tracking system for product reregistration;
  - Breakdowns in internal communication;
  - Duplication of label reviews in SRRD and RD;
  - Failure of OPP to use suspension authority to ensure timely responses;
  - Inadequate resources allocated to product reregistration.

- **Streamlining Efforts initiated by SRRD and RD**

  - SRRD streamlined its batching process for 2,4-D's 603 products resulting in more than a 50% reduction in the number of product-specific acute toxicity studies required;

- The handoff of the final, reviewed, product package from SRRD to RD was streamlined resulting in significant time savings for RD PMs;

- Instead of trickling packages to RD on a product-by-product basis, packages are transmitted from SRRD to RD only when 95% - 100% of the products are ready;

- An expedited mitigation on labels effort was piloted with propanil resulting in 40 out of 43 labels being amended with the RED-specified mitigation within 5-8 months after the RED was signed.

Recommendations

- Improve transition from RED completion into product reregistration process by convening handoff meetings to summarize RED content, mitigation and issues and to coordinate/delineate roles and responsibilities regarding any post-RED issues [*adopted by OPP management*];

- Increase participation of RD PMs in label table development to enhance quality and consistency of label language [*adopted by OPP management*];

- Implement mitigation in an expedited manner (i.e., require amended labels immediately after RED is signed that incorporate the mitigation required in the RED) when it is cost-effective based on the level of mitigation required by the RED [*adopted by OPP management*];

- Pursue electronic labels to streamline the label review process [*already under development in RD for registration];*

- Pursue additional regulatory action when registrant is in non-compliance [*adopted by OPP management*];

- Modify REDs to include explicit justification for each data requirement to be called in [*adopted by OPP management*];

- Expand streamlined batching efforts to other REDs with industry taskforces [*adopted by OPP management and being implemented for permethrin (1,185 products), MGK-264 (706 products) and PBO (1,704 products)*];

- Label review function should reside in RD [*still under consideration by OPP management*];

- Create incentives for registrants to provide expedited responses such as reduced maintenance fees [*rejected by OPP management*];

- Establish hand-off meetings when final product package sent from SRRD to RD [*adopted by OPP management*];

- Increase resource allocation to product reregistration since the external review concluded that 2018 is a more likely completion date than the 2012 date provided by OPP [*still under consideration by OPP management; would depend on future budget allocations*];

- Use SWAT teams and other strategies to reduce backlogs [*adopted by OPP management*];

- Obtain more science support for DCI justification process [*still under consideration by OPP management*];

- Incorporate quantitative performance goals for product reregistration into PARS for all managers and staff in participating divisions [*adopted by OPP management*];

- Ensure that PRISM has the functionality for integrated tracking and reporting for all critical components of the product reregistration process [*still under consideration by OPP management; would depend on future budget allocations*];

- Improve internal and external communication about the status of product reregistration [*adopted by OPP management*];

- Maintain the web site as a repository of reregistration decisions including amendments to the REDs [*adopted by OPP management*]

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